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First-In-Man IVUS Findings of the Prohealing PROTEX™ Coronary Stent System for the Treatment of Coronary Artery Disease

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Background: The PROTEX system integrates a cobalt alloy stent platform with prohealing extracellular matrix coating that facilitates rapid coverage of the stent surface by endothelial cells from the tissue and/or endothelial progenitor cells in the blood stream. This study aimed to evaluate vessel response to this novel device in human coronary lesions as assessed by IVUS.
Methods: In a first-in-man, prospective, multicenter, single-arm trial of PROTEX, serial (baseline and 6 months) IVUS was performed in 38 patients. In addition to the standard IVUS variables, a neointima-free frame ratio (number of frames without neointima/total frame number) was calculated to assess gross coverage of struts. Cross-sectional (cross-sectional narrowing: CSN) and longitudinal severity indices (% stent length with CSN >60%: IH60) of lumen encroachment by neointima were also assessed.
Results: Overall, vessel behind the stent showed a slight shrinkage during follow-up, and no case had excessive positive remodeling or late-acquired incomplete stent apposition. The neointima-free frame ratio was 1.4%, indicating almost no exposed stent struts at 6 months. In cases with significant lumen encroachment (max CSN >60%), the longitudinal severity index was 13.4%, representing focal neointimal accumulation.

	Post-procedure	6 months follow-up	p
Vessel volume (mm^3/mm)	15.3 ± 4.0	14.7 ± 3.5	0.0252
Lumen volume (mm^3/mm)	7.8 ± 1.6	5.4 ± 1.6	<0.0001
Neointimal obstruction (%)	-	28.2 ± 12.6	-
Max CSN (%)	-	45.4 ± 16.4	-
Cases with Max CSN >60% (%)	-	21.6	-
IH60 in Cases with Max CSN >60%	-	13.4 ± 16.4	-
Neointima-free frame ratio	-	1.4 ± 7.9	-
Edge Dissection (%)	6.6	0	-
Late ISA (%)	-	0	-

IH60 was defined as percent stent length with CSN >60%

CSN; cross sectional narrowing, ISA; incomplete stent apposition

Conclusion: First-in-man IVUS results of PROTEX demonstrated favorable vessel responses with nearly complete tissue coverage of struts within 6 months. Possible synergy of this prohealing stent coating and antiproliferative agents may warrant investigations.

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Vascular Healing After Endothelial Progenitor Cell Capturing Stent Implantation at 30 days

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Background: As an alternative to DES, a novel antibody-coated endothelial progenitor cell capturing (EPC) Genous (OrbusNeich Medical GmbH, Wiesbaden, Germany) stent has been developed, which has shown good results in unselected patiens. The capture of circulating endothelial progenitor cells promotes rapid endothelialization of the stent, which in turn allows shorter duration of dual-antiplatelet treatment. Optical coherence tomography (OCT) has become the method of choice for evaluating stent endothelialization and vascular healing.
Methods: We analyzed the percentage of stent strut endothelial cell coverage (binary strut coverage) and stent apposition using optical coherence tomography (OCT) and assessed the reactivity of the microcirculation using coronary flow reserve (CFR) by transthoracic echocardiography after implantation of EPC stents. A total of 20 patients with a lesion in LAD were enrolled and OCT and CFR were performed at 30 days after stent implantation.
Results: The binary stent strut coverage was 94.8 %. No thrombi were detected and the percentage of malapposed stent struts was 2.4 %. The mean NIH thickness was 108 ± 96 μm and NIH% 8.9 ± 7.4 %. Mean CFR was 2.5 ± 0.2. Two patients had abnormal CFR < 2.0 (1 restenosis and 1 de novo lesion in the target vessel).

Table. Optical tomographic measurements

Follow-up, 30 days	GENOUS (n=20)
No. of Cross Sections	336
No. of Struts	3260
Mean Lumen Area (mm2)	7.02 ± 1.51
Mean Stent Area (mm2)	7.57 ± 1.60
Mean NIH Thickness (μm)	107.9 ± 96.4
Mean NIH area (%)	8.9 ± 7.4
Binary Strut Coverage, (%)	94.8 %
Presence of Thrombi, n (%)	0 %

Conclusion: Evaluated with OCT and CFR, the Genous stent showed favorable healing properties with rapid endothelialization, low NIH% area, few malapposed struts and adequate vasodilation response at 30 days excluding patient with restenosis.

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Evaluation of Neointimal Healing of EPC-Capturing Sirolimus-Eluting COMBO Stent by Optical Coherence Tomography: The EGO-COMBO Pilot Study (interim results)

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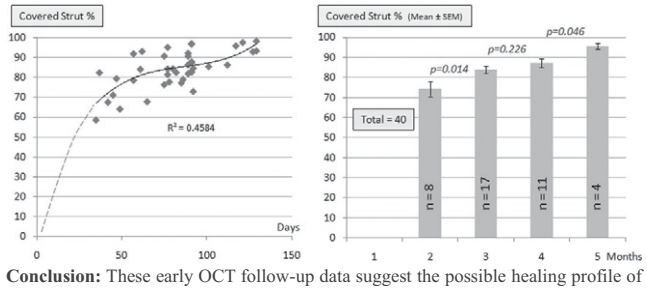
Background: COMBO Stent (OrbusNeich Medical, FL, USA) is a hybrid version of the endothelial progenitor cell (EPC) capturing GENOUS Stent, with an additional abluminal 5 μg/mm sirolimus coating, about ½ the dose of current sirolimus-eluting stent but with a similar release profile (about 90% of the drug released by 35 days) via a Surmodics SynBiosys™ bio-degradable polymer, aiming at optimal neointimal suppression similar to other DES while retaining the EPC capturing benefit (envisaged better endothelialization and less late stent thrombosis) as reported in animal models. Such combined benefits were evaluated clinically in this Study.
Methods: In this prospective, single center, pilot study, 60 patients treated by COMBO Stent were randomised to 4 monthly groups (in 1:2:2:1 ratio). OCT was performed sequentially at baseline post-stenting, at early follow-ups in 4 groups at 2nd, 3rd, 4th, and 5th month (for early neointimal healing), and at 9 months (for OCT late loss). Independent OCT core laboratory performed the covered strut % and neointima analyses, while in-house analyses further stratified the early strut coverage into 6 categories.
Results: To date, all 60 patients (30% diabetic, 87 COMBO stents implanted) were enrolled; 40 had the first OCT follow up. A total of 7004 frames and 60069 struts were analyzed. The mean percentage of covered struts (with proper apposition) was 74.4%, 84.0%, 87.4% & 95.6%, p=0.014, 0.226, & 0.046, from 2nd to 5th monthly group, respectively (refer to Figure). No MACE was recorded. Study Limitations: (1) no other DES control arm & (2) OCT classification of early strut coverage requires further validation.



Conclusion: These early OCT follow-up data suggest the possible healing profile of the new EPC-capturing COMBO DES, with near 100% strut coverage by 140 days. Nine months follow-up data are pending. Clinical data on larger patient population are needed to verify these promising imaging results.

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Twelve-Month Clinical Efficacy and Safety of Zotarolimus- versus Everolimus-Eluting Stents in a Series of Asian Population

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Background: Recently, newer generation drug-eluting stents (DESs) have been widely used with improved performance and safety. However, there have been limited data comparing angiographic and clinical outcomes of individual newer generation DESs in real world clinical practice, specifically in Asian population.
Methods: A total of 608 patients (pts) underwent percutaneous coronary intervention (PCI) with Zotarolimus-eluting stents (ZES group; Endeavor ResoluteTM, n=238 pts) and Everolimus-eluting stents (EES group; PromusTM or XienceTM n=370 pts) were enrolled for this study. Angiographic outcomes at 6 months and major clinical outcomes up to 12 months were compared.
Results: There were no significant differences in baseline clinical characteristics between the two groups. At 6 months, angiographic outcomes were similar between the two groups. At 12 months, there was a trend toward higher incidence of non-target lesion revascularization (TLR) target vessel revascularization (TVR) in the EES group; however other major clinical outcomes including mortality, Q-wave myocardial infarction (MI), repeat PCI and major adverse cardiac events (MACEs) were similar between the two groups up to 12 months (Table)

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